

## Summary of the dossier: Vitamin D2 Mushroom Powder

Applicant: Monterey Mushrooms, Inc., 260 Westgate Drive, Watsonville, CA 95076, USA

This is an application for authorisation of vitamin D2 mushroom powder as a novel food ingredient in the European Union (EU). The application has been prepared in accordance with the requirements of Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, the European Food Safety Authority (EFSA) Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283 and EFSA's Administrative guidance on the submission of applications for authorisation of a novel food pursuant to Article 10 of Regulation (EU) 2015/2283.

Vitamin D2 mushroom powder is an ingredient produced by tightly controlled exposure of *A. bisporus* mushrooms to UV light (which catalyses the conversion of endogenous ergosterol within the mushrooms to vitamin D2), followed by dehydration and grinding into a powder. The nutritional content of mushrooms exposed to UV light is unchanged, with the exception of the intended increase in vitamin D2 content. *A. bisporus* mushrooms have a long history of consumption within and outside of the EU and UV irradiated *A. bisporus* mushrooms also have a history of consumption in the EU, as they have been approved as a novel food ingredient since 2016. UV irradiation has been applied to other approved novel foods, UV treated baker's yeast (*Saccharomyces cerevisiae*), UV treated bread and UV treated milk, all of which are listed under Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods.

Analysis of several independent, representative batches of vitamin D2 mushroom powder demonstrates that the manufacturing process produces a consistent ingredient that is absent of chemical or microbiological contaminants. Vitamin D2 mushroom powder is intended for use in several food and beverage categories, as well as in food supplements. The proposed maximum use levels of vitamin D provided by vitamin D2 mushroom powder are intended to provide the required amounts to be deemed as a "source" of vitamin D, as stipulated in Regulation (EC) No 1924/2006, ensuring that it is of no nutritional disadvantage for the consumer. At these use levels, even the most conservative worst-case estimates for vitamin D2 intakes from all proposed uses of vitamin D2 mushroom powder (as well as cumulative exposure to vitamin D2 from vitamin D2 mushroom powder and to vitamin D from the background diet) do not exceed the tolerable upper limits for vitamin D established by EFSA, for all population groups.

Given its source, nature and intended uses, it is considered that vitamin D2 mushroom powder is safe under the intended conditions of use.